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December 23, 2003

Re:

Docket No. 02N-0276 – Registration of Food Facilities under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002  
Attn: Ms. Leslye Fraser

Docket No. 02N-0278 – Prior Notice of Imported Food under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002  
Attn: Ms. Deborah Ralston

Dear Ms. Fraser and Ms. Ralston:

The following comments are submitted on behalf of my client, the French Federation of Exporters of Wines & Spirits (FEVS), the representative body of the French wines and spirits industry and trade. FEVS has five hundred and fifty (550) members, which account for ninety percent (90%) of total French exports of wines and spirits.

The United States market accounted for approximately twenty two percent (22%) of French wine and spirits exports in calendar year 2002. Consequently, the U.S. regulation of these industries has important consequences for FEVS and its members.

As background information, you will find an Exhibit with an explanation of French wine production and label terms entitled “French wine production and marketing involve several participants and steps.”

The Food and Drug Administration (FDA) has published Interim Final Rules regarding the *Registration of Food Facilities under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002* and *Prior Notice of Imported Food under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002*, both of which create serious impediments to French wine and spirits exports and which require important changes in traditional commercial practices.

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In response to the request for public comments, FEVS is pleased to submit its views regarding four (4) general topics related to the Interim Final Rules:

*The Interim Final Rules are likely to have negative effects on business confidentiality and trade secrets, as facility registration numbers are divulged then used without authorization. The Interim Final Rules should be interpreted and applied so as to deter gray market sales.*

*The Interim Final Rules, in particular the requirement for a U.S. Agent, alter traditional commercial practices unnecessarily and add costs to each transaction, with important negative consequences for small and medium sized businesses, and for new entrants to the market.*

*The claimed compatibility of the Interim Final Rules as national security measures with the rules of the World Trade Organization is unconvincing and is more tenuous if the measures will be used to protect the safety of the U.S. food supply.*

In addition, FEVS offers its comments regarding two more specific issues, which have special importance for the wine and spirits sector.

*The scheme of product names used in the Interim Final Rules must not infringe on geographical indications, such as Champagne and Cognac.*

*The "manufacturer" must be defined in both Interim Final Rules. FEVS suggests that the common definition should define the manufacturer as the last entity to conduct a processing operation, e.g., including bottling but excluding labeling.*

Each of the above comments is explained in detail in the enclosed Comments.

FEVS and I would be pleased to explain further, to answer your questions regarding these comments and to discuss the impact of the Interim Final Rules on the French wine and spirits sector.

Sincerely,



Marsha A. Echols

enclosure